

SPECIALTY GUIDELINE MANAGEMENT

TRODELVY (sacituzumab govitecan-hziy)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Trodelvy is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

B. Compendial Uses

Recurrent or stage IV (M1) triple-negative breast cancer in patients who have received at least two prior therapies for metastatic disease

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Test results confirming that the cancer cells are negative for the following receptors:

- A. Human epidermal growth factor receptor 2 (HER2)
- B. Estrogen
- C. Progesterone

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer

Authorization of 12 months may be granted for treatment of recurrent or metastatic triple-negative breast cancer (mTNBC) when all of the following criteria are met:

1. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for all of the following receptors:
 - i. Human epidermal growth factor receptor 2 (HER2)
 - ii. Estrogen
 - iii. Progesterone
2. The member has received at least two prior therapies for metastatic disease

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Reference number(s)
3818-A

V. REFERENCES

1. Trodelvy [package insert]. Morris Plains, NJ: Immunomedics; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed May 13, 2020.